

⑫ **EUROPEAN PATENT SPECIFICATION**

- ⑬ Date of publication of patent specification: 10.10.90      ⑮ Int. Cl.<sup>5</sup>: **A 61 F 5/44, A 61 L 31/00**  
⑭ Application number: **84307354.5**  
⑯ Date of filing: **25.10.84**

⑰ **Disposable bags.**

⑲ Priority: **15.11.83 GB 8330414**

⑳ Date of publication of application:  
**29.05.85 Bulletin 85/22**

㉑ Publication of the grant of the patent:  
**10.10.90 Bulletin 90/41**

㉒ Designated Contracting States:  
**BE CH DE FR GB IT LI NL SE**

㉓ References cited:  
**DE-A-2 518 362**  
**US-A-3 550 592**  
**US-A-4 242 408**  
**US-A-4 372 311**

㉔ Proprietor: **IMPERIAL CHEMICAL INDUSTRIES PLC**  
**Imperial Chemical House, Millbank**  
**London SW1P 3JF (GB)**

㉕ Inventor: **Holmes, Paul Arthur**  
**The Chestnuts Thornton-le-Beans**  
**Northallerton North Yorkshire (GB)**

㉖ Representative: **Gratwick, Christopher et al**  
**Imperial Chemical Industries PLC Legal**  
**Department: Patents PO Box 6 Bessemer Road**  
**Welwyn Garden City Herts, AL7 1HD (GB)**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European patent convention).

Courier Press, Leamington Spa, England.

**EP 0 142 950 B1**

## EP 0 142 950 B1

### Description

This invention relates to disposable bags and in particular to body-waste bags for receipt of faeces and/or urine, for example incontinence bags and bed pan liners.

5 Incontinence bags are often worn by the incontinent or those who have undergone certain surgical operations, e.g. colostomy, so that the wearer's mobility is not restricted by virtue of the incontinence and/or operation.

Disposal of the bags after use creates problems since they are liable to cause obstructions in sewage pipes and in sewage treatment plants.

10 It has been proposed in US-A-4372311 to make disposable articles from a water soluble polymer coated with a degradable polymer. Amongst the degradable polymers listed therein is poly(3-hydroxybutyrate). That specification suggests that upon degradation of the degradable polymer, the water soluble polymer can dissolve and hence obstruction of sewage pipes and sewage treatment plants would be avoided.

15 While 3-hydroxybutyrate polymers are well suited to the manufacture of body-waste bags, whether alone or as a coating on a water soluble polymer, by virtue of their good water and vapour impermeability characteristics, their rate of degradation is often too slow to avoid the formation of the aforementioned obstructions.

We have found that the rate of degradation can be markedly increased by modification of the pH of the 20 bag contents.

Accordingly the present invention provides a method of disposal of a body-waste bag comprising a 3-hydroxybutyrate polymer and containing human faeces and/or urine including the steps of modifying the pH of the contents of the bag to a pH of at least about 12, and thereafter introducing said bag and contents into a sewage system.

25 The pH is conveniently modified by addition of a base to the bag contents. The base is preferably added as a solid.

Suitable bases include sodium hydroxide and sodium carbonate. To avoid handling hazards, the base is preferably added to the bag contents in the form of a container e.g. a capsule or sachet containing the requisite amount of the base, said container being made from a water soluble material such as polyvinyl 30 alcohol. Alternatively the base can be added in the form of a pellet or powder having a coating of a suitable water soluble material, e.g. a water soluble polymer or sugar.

The amount of base that needs to be added to each bag will depend on the nature of the base, i.e. its strength, and on the volume, pH, and buffering capacity of the bag contents. Human faeces and urine generally have a pH in the range about 4.5 to about 8.5, but will not generally exert a significant buffering 35 capability.

The useful, i.e. "working" capacity of the bag is generally no more than about 50% of the actual, i.e. total, capacity of the bag.

Generally it is desirable that the user adds a standard amount, preferably a prepacked amount, of the base to the bag contents irrespective of the degree of filling of the bag to be disposed or of the pH of the 40 contents.

Accordingly the amount of base added is desirably sufficient to increase the pH of the contents of a bag half full of the body-waste at pH about 4.5 to at least about 12.

Where the base is sodium hydroxide or carbonate, the amount of base required is thus at least about 0.2 g of sodium hydroxide or at least about 5 g of sodium carbonate monohydrate per 100 ml of bag total 45 capacity. Preferably the amount of base employed is 0.3 to 3 g of sodium hydroxide or 6 to 15 g of sodium carbonate monohydrate per 100 ml of bag total capacity.

The invention also provides a package including

(i) at least one body-waste bag comprising a 3-hydroxybutyrate polymer, and

50 (ii) sufficient of basic material to modify the pH of the contents of all of the bags in said packages, when said bags are half filled with human faeces and/or urine, to a value of at least about 12.

Consequently such a package should contain, where the base is sodium hydroxide or sodium carbonate, at least 0.2 xn, preferably 0.3 xn to 3 xn g of sodium hydroxide or 5 xn, preferably 6 xn to 15 xn g of sodium carbonate monohydrate, where n is the number of bags in the package and each bag has a total capacity of 100 ml.

55 Each bag preferably has a total capacity within the range 50 to 500 ml.

Accordingly the invention further provides a package including at least one body waste bag comprising a 3-hydroxybutyrate polymer and a base selected from sodium hydroxide and sodium carbonate monohydrate, the quantity of base in the package being at least 0.2 xn g of sodium hydroxide or at least 5 xn g of sodium carbonate monohydrate, where n is the number of said body waste bags in the 60 package and each body waste bag has a total capacity of 100 ml.

In order to improve wetting of the 3-hydroxybutyrate polymer by the bag contents, in some cases the addition of a surfactant may be desirable. Such a surfactant may be incorporated in the package either as a separate ingredient or in admixture with the basic material.

65 The bag is conveniently constructed from a film: the film may be a laminate of a water soluble polymer film, such as a polyvinyl alcohol or polyethylene oxide film, and a 3-hydroxybutyrate polymer film or

## EP 0 142 950 B1

coating with the latter on the interior side of the bag. Preferably, where a laminar structure is employed, the laminate also has a film or coating of the 3-hydroxybutyrate polymer on the external surface of the bag so that the water soluble polymer is sandwiched between the 3-hydroxybutyrate polymer layers. In such a laminar or sandwich construction the, or each, 3-hydroxybutyrate polymer layer preferably has a thickness of 5 to 25  $\mu\text{m}$  and the water soluble polymer film preferably has a thickness of 25 to 75  $\mu\text{m}$ .

Alternatively the film used to make the bag may be of non-laminar construction and may be a 3-hydroxybutyrate film or sheet, preferably of thickness 25 to 100  $\mu\text{m}$ .

3-Hydroxybutyrate polymers may be made microbiologically, for example by the techniques described in European Patent Publications 15669 and 46344. Microbiologically produced 3-hydroxybutyrate copolymers, for example as described in European Patent Publications 52459 and 69497 may be employed if desired: the use of copolymers, for example containing 10 to 25, particularly 15 to 20 mole % of 3-hydroxyvalerate units may in some cases be advantageous to lower the modulus of the 3-hydroxybutyrate polymer since then bags made from a film of such copolymers are less liable to make rustling noises upon movement of the wearer.

The 3-hydroxybutyrate polymer may be extracted from the micro-organism by the techniques disclosed in European Patent Publications 15123, 36699, 46017 and 46335. Films or coatings of the 3-hydroxybutyrate polymer may be made by solution coating techniques or by melt extrusion.

In some cases it may be desirable to fabricate the film or coating from a plasticised 3-hydroxybutyrate polymer: suitable plasticisers include aryl sulphonamides and triphenyl phosphate.

The use of an aryl sulphonamide, such as o,p-toluene sulphonamide, as a plasticiser, in addition to improving the physical characteristics of the film, has the further advantage that, upon addition of the base to the bag contents, the sulphonamide tends to give the corresponding aryl sulphonate which acts as a transesterification catalyst thereby enhancing the rate of breakdown of the 3-hydroxybutyrate polymer.

The invention is illustrated by the following Examples.

### Example 1

In this example the effect of acids and bases on the degradation rate of a film of a 3-hydroxybutyrate polymer is illustrated.

A film of thickness 40  $\mu\text{m}$  was cast from a solution of a 3-hydroxybutyrate copolymer containing 17 mole % of 3-hydroxyvalerate units in methylene chloride. The solution also contained 20% by weight, based on the weight of the 3-hydroxybutyrate copolymer of o,p-toluene sulphonamide as a plasticiser. The film was cut into strips 6 cm long and 1 cm wide. The film samples were immersed in the appropriate aqueous solution at room temperature and agitated gently. Samples were removed at intervals and the tensile properties assessed. The results were as follows:

Solution	pH	Tensile properties of film
1. water	~7	negligible change after 6 hours immersion
2. 2N HCl	<1	negligible change after 6 hours immersion
3. 3N NaOH	>14	complete disintegration after about 20—30 minutes immersion
4. 2N NaOH	>14	
5. N NaOH	~14	film rapidly lost strength and disintegrated after about 6 hours immersion
6. N/2 NaOH	>13	film rapidly became brittle. Wetting of the film could be improved by addition of a surfactant. As the proportion of surfactant increased in the range 0.025 to 0.5% by weight of the solution, the rate of degradation of the film increased.

### Example 2

A polyvinyl alcohol film of thickness 40  $\mu\text{m}$  was coated on one side with the 3-hydroxybutyrate copolymer containing solution employed to make the cast film in Example 1, and the solvent allowed to evaporate to give a plasticised 3-hydroxybutyrate copolymer coating of 15  $\mu\text{m}$  thickness.

The coated film was then fabricated into a colostomy bag of 100 ml total capacity with the 3-hydroxybutyrate copolymer coating on the inside.

To dispose of the bag after addition of about 50 ml of mixture of human urine and faeces, a pellet of 2 g

## EP 0 142 950 B1

of sodium hydroxide is added to the bag contents to raise the pH to above 14 and then the bag is sealed and placed in a W.C. pan.

Within a short period the bag disintegrates and largely dissolves enabling the pan to be flushed without risk of blockage of the sewage pipes.

5

### Example 3

A sachet was prepared from the plasticised copolymer film described in Example 1 by heat sealing two layers of film along three right angled edges. The resulting sachet was 15 cm long and 10 cm across the open end. The sachet was then half filled with approximately 50 ml of an aqueous medium designed to  
10 simulate the consistency of faecal wastes. This medium was prepared by adding 2.5 kg of sharp sand of particle size between 150 and 420  $\mu\text{m}$  to 1 litre of an aqueous solution containing 20 g of high viscosity sodium carboxymethyl cellulose.

No leakage of the contents of the sachet occurred over a period of several days.

2 g of caustic soda prills were dropped into the half full sachet. The heat sealed edges began to leak  
15 after only a few minutes. The leaking sachet was then suspended over an empty beaker. The sachet failed catastrophically, releasing the contents within 5 minutes of addition of the caustic soda.

Similar results were obtained when the caustic soda was added in the form of prills sealed into a sachet fabricated from a water soluble polyvinyl alcohol (PVA) film since the PVA film disintegrated within a few seconds of being added to the sachet contents.

20

### Example 4

A solution containing 10% by weight of the copolymer employed in Example 1 and 2% by weight of o,p-toluene sulphonamide dissolved in chloroform was carefully spread on a polyvinyl alcohol film of thickness 40  $\mu\text{m}$  and allowed to dry to give a plasticised copolymer coating of 15  $\mu\text{m}$  thickness. The coated  
25 film was then turned over and a similar coat was applied to the other side of the polyvinyl alcohol film.

A sachet of this laminated film was prepared by heat sealing as described in Example 3 and 50 ml of the viscous faecal waste simulating medium added. No leakage of the contents were observed over three days. However, when the 2 g of caustic soda were added, leakage occurred at the seal almost immediately and catastrophic failure of the seals occurred within 20 seconds causing release of the contents. The film  
30 remaining had the consistency of wet toilet paper and would not be expected to cause blockages in a domestic sanitation system.

### Claims

35 1. A package including at least one body-waste bag comprising a 3-hydroxybutyrate polymer, and sufficient of a basic material to modify the pH of the contents of all the body-waste bags in the package, when the bags are half filled with human faeces and/or urine, to a value of at least about 12.

2. A package including at least one body-waste bag comprising a 3-hydroxybutyrate polymer and a base selected from sodium hydroxide and sodium carbonate monohydrate, the quantity of base in the  
40 package being at least 0.2 xn g of sodium hydroxide or at least 5 xn g of sodium carbonate monohydrate, where n is the number of said body-waste bags in the package and each body-waste bag has a total capacity of 100 ml.

3. A package according to claim 1 or claim 2 wherein the base is in a number of prepacked amounts at least equal to the number of bags in the package.

45 4. A package according to claim 3 wherein the base is prepacked in containers formed from a water-soluble polymer, each container containing the amount of base required to be added to one bag.

5. A package according to any one of claims 1 to 4 also containing a surfactant.

6. A package according to any one of claims 1 to 5 wherein each bag is fabricated from a film of a water-soluble polymer coated or laminated, at least on one surface, with a layer of a 3-hydroxybutyrate polymer,  
50 each bag having a 3-hydroxybutyrate polymer layer at least on the interior surface of the bag.

7. A package according to any one of claims 1 to 6 wherein the 3-hydroxybutyrate polymer is a 3-hydroxybutyrate/3-hydroxyvalerate copolymer.

8. A package according to any one of claims 1 to 7 wherein the 3-hydroxybutyrate polymer contains an aryl sulphonamide plasticiser.

55 9. A method of disposal of a body-waste bag comprising a 3-hydroxybutyrate polymer and containing human faeces and/or urine including the steps of modifying the pH of the contents of the bag to a pH of at least about 12, and thereafter introducing said bag and contents into a sewage system.

### Patentansprüche

60

1. Verpackung, enthaltend wenigstens einen Beutel für Ausscheidungsprodukte, der ein 3-Hydroxybutyrat-Polymer enthält, und eine Menge einer basischen Substanz, die zum Abändern des pH des Inhalts aller in der Verpackung vorhandenen Beutel für Ausscheidungsprodukte auf einen Wert von wenigstens etwa 12 ausreicht, wenn die Beutel halb mit Stuhl und/oder Harn gefüllt sind.

65 2. Verpackung, enthaltend wenigstens einen Beutel für Ausscheidungsprodukte, der ein 3-Hydroxy-

## EP 0 142 950 B1

butyrat-Polymer enthält, und eine Base, die aus Natriumhydroxid und Natriumcarbonatmonohydrat ausgewählt ist, wobei die Menge der Base in der Verpackung wenigstens  $0,2 \cdot n$  g Natriumhydroxid oder wenigstens  $5 \cdot n$  g Natriumcarbonatmonohydrat beträgt, wobei  $n$  die Zahl der Beutel für Ausscheidungsprodukte in der Verpackung ist und jeder Beutel für Ausscheidungsprodukte ein Gesamt-

5 Fassungsvermögen von 100 ml hat.  
3. Verpackung nach Anspruch 1 oder Anspruch 2, bei der die Base in Form von im voraus verpackten Mengen vorhanden ist, deren Zahl wenigstens gleich der Zahl der in der Verpackung vorhandenen Beutel ist.

4. Verpackung nach Anspruch 3, bei der die Base im voraus in Behälter, die aus einem wasserlöslichen Polymer gebildet sind, verpackt worden ist, wobei jeder Behälter die Basenmenge enthält, die einem Beutel

10 zugesetzt werden muß.

5. Verpackung nach einem der Ansprüche 1 bis 4, die auch eine oberflächenaktive Substanz enthält.

6. Verpackung nach einem der Ansprüche 1 bis 5, bei der jeder Beutel aus einer Folie aus einem wasserlöslichen Polymer, die wenigstens auf einer Oberfläche mit einer Schicht aus einem 3-Hydroxybutyrat-Polymer beschichtet oder laminiert ist, hergestellt ist, wobei jeder Beutel wenigstens auf

15 der Innenfläche des Beutels eine Schicht aus 3-Hydroxybutyrat-Polymer aufweist.

7. Verpackung nach einem der Ansprüche 1 bis 6, bei der das 3-Hydroxybutyrat-Polymer ein 3-Hydroxybutyrat/3-Hydroxyvalerat-Copolymer ist.

8. Verpackung nach einem der Ansprüche 1 bis 7, bei der das 3-Hydroxybutyrat-Polymer ein

20 Arylsulfonamid-Plastifizierungsmittel enthält.

9. Verfahren zum Beseitigen eines Beutels für Ausscheidungsprodukte, der ein 3-Hydroxybutyrat-Polymer enthält und in dem Stuhl und/oder Harn enthalten ist, mit den Schritten des Abänderns des pH des Inhalts des Beutels auf einen Wert von wenigstens etwa 12 und des danach erfolgenden Einführens des Beutels und des Inhalts in eine Abwasseranlage.

### 25 Revendications

1. Conditionnement, caractérisé en ce qu'il comprend au moins un sac à déchets corporels comprenant un polymère de 3-hydroxybutyrate et suffisamment de matière basique pour modifier le pH du contenu de

30 tous les sacs à déchets corporels dans le conditionnement lorsque les sacs sont à moitié remplis d'urine et/ou de fèces humaines, à une valeur d'au moins environ 12.  
2. Conditionnement, caractérisé en ce qu'il comprend au moins un sac à déchets corporels comprenant un polymère de 3-hydroxybutyrate et une base choisie parmi l'hydroxyde de sodium et le carbonate de sodium monohydraté, la quantité de base dans le conditionnement étant d'au moins  $0,2 \times n$  g d'hydroxyde

35 de sodium ou d'au moins  $5 \times n$  g de carbonate de sodium monohydraté, où  $n$  est le nombre de ces sacs à déchets corporels dans le conditionnement et où chaque sac à déchets corporels a une capacité totale de 100 ml.

3. Conditionnement suivant la revendication 1 ou la revendication 2, caractérisé en ce que la base est dans un nombre de quantités préconditionnées au moins égal au nombre de sacs dans le conditionnement.

4. Conditionnement suivant la revendication 3, caractérisé en ce que la base est préconditionnée dans

40 des récipients formés à partir d'un polymère soluble dans l'eau, chaque récipient contenant la quantité de base requise à ajouter à chaque sac.

5. Conditionnement suivant l'une quelconque des revendications 1 à 4, caractérisé en ce qu'il contient aussi un tensio actif.

6. Conditionnement suivant l'une quelconque des revendications 1 à 5, caractérisé en ce que chaque

45 sac ayant une couche de polymère de 3-hydroxybutyrate au moins sur la surface intérieure du sac.

7. Conditionnement suivant l'une quelconque des revendications 1 à 6, caractérisé en ce que le polymère de 3-hydroxybutyrate est un copolymère de 3-hydroxybutyrate/3-hydroxyvalérate.

8. Conditionnement suivant l'une quelconque des revendications 1 à 7, caractérisé en ce que le

50 polymère de 3-hydroxybutyrate contient un plastifiant arylsulfonamide.

9. Méthode pour jeter un sac à déchets corporels comprenant un polymère de 3-hydroxybutyrate et contenant des fèces et/ou de l'urine humaines, caractérisée en ce qu'elle comprend les étapes de

modification du pH du contenu du sac à un pH d'au moins environ 12, puis d'introduction du sac et de son contenu dans un système d'égout.